

CLAIMS:

1. A process for the induction of immunoglobulin A (IgA) in a mammal which process comprises:
 - 5 (a) actively immunising a pregnant mammal with an antigen by any two routes of administration selected from intramammary (IMM), intraperitoneal (IP) and intramuscular (IM); and
 - (b) actively immunising said mammal with an antigen by a third administration route selected from intramammary (IMM), intraperitoneal (IP) and intramuscular (IM); with the proviso that all three administration routes are different.
- 10 2. A process according to claim 1 wherein in step (a) the two routes of administration selected are IP and IM and in step (b) the third route of administration is IMM.
- 15 3. A process according to claim 1 or claim 2 wherein the two active immunisations of step (a) are effected sequentially, discontinuously or concurrently.
- 20 4. A process according to claim 3 wherein the two active immunisations of step (a) are effected concurrently.
5. A process according to any one of claims 1 to 4 wherein steps (a) and (b) are effected sequentially, discontinuously or concurrently.
- 25 6. A process according to any one of claims 1 to 5 wherein steps (a) and (b) are repeated once or twice prior to parturition.
7. A process according to any one of claims 1 to 5 wherein step (a) is repeated twice, prior to parturition.
- 30 8. A process according to claim 7 wherein each step (a) is effected at 2 to 8 week intervals.
9. A process according to claim 8 wherein each step (a) is effected at 2 to 4 week intervals.
- 35 10. A process according to any one of claims 6 to 9 wherein step (a) is effected 6 to 14 weeks prior to parturition, first repeat step (a) at 2 to 10 weeks prior to parturition,

and the final step (a) at 1 to 4 weeks prior to parturition.

11. A process according to claim 10 wherein step (a) is effected 8 to 12 weeks prior to parturition, first repeat step (a) at 4 to 8 weeks prior to parturition, and the final step (a) at 1 to 4 weeks prior to parturition.
5
12. A process according to claim 11 wherein step (a) is effected 8 weeks prior to parturition, first repeat step (a) at 4 weeks prior to parturition, and the final step (a) at 1 week prior to parturition.
10
13. A process according to any one of claims 6 to 12 wherein step (b) is repeated once prior to parturition.
15
14. A process according to any one of claims 6 to 13 wherein the (b) steps are effected at 1 to 6 week intervals.
15
15. A process according to claim 14 wherein the (b) steps are effected at 2 week intervals.
20
16. A process according to claim 13 or claim 14 wherein step (b) is effected 3 to 12 weeks prior to parturition, and repeat step (b) at 1 to 10 weeks prior to parturition.
25
17. A process according to claim 16 wherein step (b) is effected 4 to 8 weeks prior to parturition and repeat step (b) 2 to 4 weeks prior to parturition.
18. A process according to claim 17 wherein step (b) is effected 4 weeks prior to parturition and repeat step (b) at 2 weeks prior to parturition.
30
19. A process for the production of mammalian milk containing immunoglobulin A (IgA), which process comprises:
 - (a) induction of IgA according to the process of any one of claims 1 to 18; and
 - (b) collecting milk containing IgA from said mammal.
35
20. A process according to any one of claims 1 to 19 wherein the antigen comprises at least one of the group of bacteria, yeasts, viruses, mycoplasmas, proteins, haptens, animal tissue extracts, plant tissue extracts, spermatozoa, fungi, pollens,

dust and a complex of antigens.

21. A process according to claim 20 wherein the antigen is a bacterial antigen.
- 5 22. A process according to claim 21 wherein the bacterial antigen is selected from the group consisting of *Escherichia*, *Staphylococcus*, *Streptococcus*, *Salmonella*, *Pneumonococcus*, *Helicobacter*, *Cryptosporidiosus*, *Campylobacter* and *Shigella*.
- 10 23. A process according to claim 22 wherein the bacterial antigen is *E.coli*.
24. A process according to claim 20 wherein the antigen is a yeast antigen.
25. A process according to claim 24 wherein the yeast is *Candida albicans*.
- 15 26. A process according to claim 20 wherein the antigen is a protein antigen.
27. A process according to claim 26 wherein the protein antigen is tumour necrosis factor.
- 20 28. A process according to claim 20 wherein the antigen is a complex of antigens.
29. A process according to claim 28 wherein the complex of antigens comprises *E. coli*, rotavirus and coronavirus.
- 25 30. A process according to any one of claims 1 to 29 wherein the antigen is formulated as a suspension.
31. A process according to any one of claims 1 to 30 wherein the antigen is administered together with an acceptable carrier, diluent, buffer, and/or adjuvant.
- 30 32. A process according to claim 31 wherein the antigen is administered together with an adjuvant.
33. A process according to claim 32 wherein the adjuvant is selected from Freund's complete adjuvant (FCA), Freund's incomplete adjuvant (FIC) adjuvant 65, cholera toxin B subunit, alhydrogel; or *bordetella pertussis*, muramyl dipeptide, cytokinins and saponin. Oil based adjuvants and in particular FCA and FIC are preferred

34. A process according to claim 33 wherein the adjuvant is Freunds incomplete adjuvant.

5 35. A process according to any one of claims 1 to 34 wherein the antigen is administered together with an antibiotic.

36. A process according to any one of claims 1 to 35 wherein the antigen administered in each immunising process, and at each site, is the same or different.

10 37. A process according to claim 36 wherein the antigen administered in each immunising process, and at each site, is the same.

38. The process according to any one of claims 1 to 37 wherein the mammal immunised is selected from the group consisting of cows, goats and sheep.

15 39. A process according to claim 38 wherein the mammal is a dairy cow.

40. IgA produced in accordance with the process of any one of claims 1 to 39.

20 41. A process for the production of mammalian milk containing IgA, which process comprises:
(a) induction of IgA according to the process of any one of claims 1 to 39; and
(b) collecting milk containing said IgA from said mammal.

25 42. IgA containing mammalian milk produced in accordance with the process of claim 41.

43. IgA isolated from the mammalian milk of claim 42.

30 44. The IgA of claim 43 which is purified IgA.

45. Use of the IgA of claim 40 or claim 44 as, or in the preparation of, pharmaceutical, cosmetic, and/or veterinary compositions.

35 46. Use of the IgA of any one of claims 42 to 44 as, or in the preparation of, food products and/or dietary supplements.

ADD
A2